Transcatheter Aortic Valve Implantation (TAVI) Past, Present and Future…

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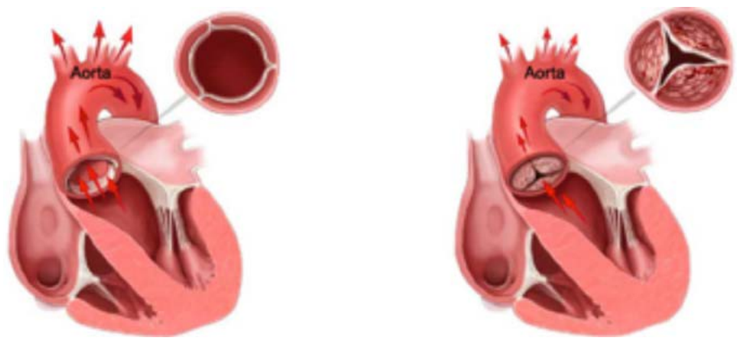
Aortic valve stenosis (AS) is the most frequent aquired heart valve disease. It is a disease process in which there is mechanical obstruction to blood flow caused by a narrowing of the aortic valve (Figure 1). AS is the most common cause of calcific degeneration, which normally presents during the seventh and eighth decades of life[1]. According to epidemiologic studies, the number of adults living above 75 years will double in 2050[2]. Incidence of degenerative aortic stenosis is on rise as well. It might reach 41% in a population in which the mean age is 81 years[3]. The disease is characterized by a long asymptomatic phase followed by rapid progression of symptoms that consists of: angina, syncope and dyspnea. Survival after the onset of symptoms is 50% at two years and goes down to 20% at five[4]. Until recently, Surgical Aortic Valve Replacement (SAVR) was the only curative treatment available and formed the backbone of management for most patients with AS [5].



A B

Figure 1: A: Aortic blood flow across normal aortic valve. B: Reduced aortic blood flow across AS Adapted from: https://www.johnmuirhealth.com/health-education/conditions-treatments/lungs-heart-blood/aortic-stenosis.html

Never less, previous studies published between 1995 and 2006 showed that 30-60% of AS are not referred to surgery6,[7]. Despite the outstanding outcomes achieved by surgery in the young patients, this wasn't enough to convince physician to refer all their diagnosed patients to the surgical team. Even when they did, this was delayed. As such, the accompanying comorbidities placed these patients at high or prohibitive risk for complications associated with surgical treatment. The high rates of postoperative death and high complication rates were high and rendered these patients not eligible for surgical replacement[8].

Thus, for years, these elderly patients were considered unsuitable for surgery and unsatisfactory medical therapy was their only choice. In 2002, Professor Alain Cribier, a French interventional cardiologist, had the brilliant idea of transcatheter aortic valve implantation (TAVI)[9]. It consists of puncturing a peripheral artery, introducing a biological valve fixed over a metallic stent inside the arterial bed, crossing the AS and implanting the neo valve without opening the chest (Figure 2). For the first time, TAVI came to complete the health care algorithm and proposes for the untreated population a real solution for their AS.

Time was needed for physicians to make this technique reproducible.

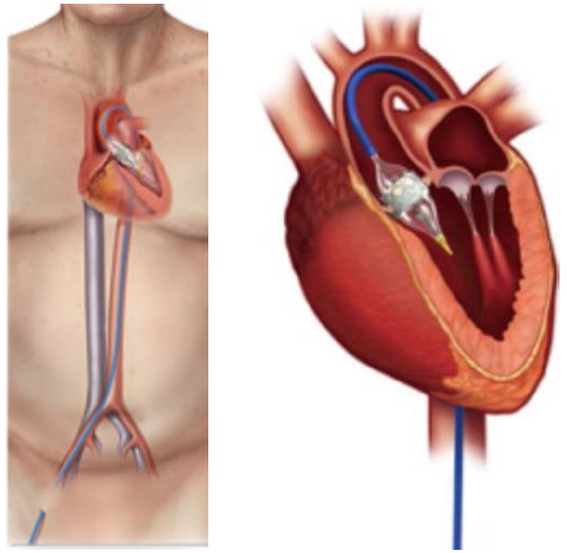


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Figure 2: A: Transfemoral approach for transcatheter aortic valve implantation Adapted from: http://edwlifes.vo.llnwd.net/o10/newheartvalve/tinymcefiles/TAVR_body_images-updated-ta-1.png. B: The valve is delivered via a catheter through the femoral artery. Source: Edwards LifeSciences Corporation.

They realized that Collaboration of all health care providers like geriatricians, cardiologists, interventional cardiologists, Surgeons and radiologists is the key of procedural success in maximum-security circumstances for their patients. In 2012, this collaboration known under the name of "Heart Team" became mandatory. Scientific authorities adopted it as fundamental criterion before starting any TAVI program.[10,11]

Sixteen years after the first procedure, the material used was smaller, more adapted and less traumatic. Lower incidence of procedural complication was then due to a better understanding of risk factors and a better selection of candidates. In addition, treatment of procedural complication was studied very seriously and solutions became possible in most of the cases[12].

All these achievements gave the heart team motivation to extend indications of this "less invasive" strategy. Several serious multinational studies were performed comparing TAVI to Standard Aortic valve surgery. Results were comparable and sometimes better, leading TAVI to become an acceptable alternative to treat calcified aortic stenosis in inoperable, high risk and also intermediate risk patients[13,14].

A B

Figure 3: A: Evolute–R Corevalve, Medtronic®. Adapted from https://www.medtronic.com/us-en/patients/treatments-therapies/transcatheter-aortic-valve-replacement/about/tavr-heart-valve.html. B: Sapien 3 Edwards TM transcatheter aortic valve. Adapted from https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3

It is thus worth emphasizing that patient selection for TAVI remains a challenge and requires a multidisciplinary approach. According to the American Heart Association/ American College of Cardiology (AHA/ACC) joint statement, patients with severe symptomatic AS and moderate or severe surgical risk may be considered for TAVI[10].

The question remains on whether TAVI can be a good alternative to surgery in low risk patients [15].
Currently, there are several ongoing studies involving younger and low risk patients. Decisions on management of this category of patients remain pending the research outcomes. An upcoming two –year follow up study on TAVI on low risk patients will be published in 2018 which may open a new horizon for TAVI in this category of patients. The outcomes achieved thus may help advance TAVI indication to reach a larger population with younger age.

One of the biggest questions that remain a challenge is the durability of the bioprosthetic transcatheter aortic valve in a long-term setting (>5 years). This is seriously considered when applying this technology to younger patients. It is as much important as low rates of perioperative complications and mortality. Ensuring durability of the device is imperative prior to this procedure being offered to younger and lower-risk patients knowing that there is excellent durability of surgically sutured valves that exceeds 17 years even in elderly population[16]. Does the "crimped valve" do as well as the surgical valve?

Well…in a "First look" report published in 2017 about long-term durability of the first generation of transcatheter heart valves, data revealed a significant increase in degeneration rates between 5-7 years after TAVI. Estimate of TAVI degeneration (resulting in at least moderate stenosis AND/OR regurgitation) was ~50% within 8 years. Studies are still ongoing to validate that new generations of these valves are giving better results [17].

It is the responsibility of the physicians to carefully choose their patients for TAVI and be aware of its indications. For this reason the AHA/ACC valvular heart disease management guidelines make a class I recommendation for a Heart Team approach to TAVI selection and care[10]. The team should consist of an interventional cardiologist, a cardiac surgeon, a cardiac anesthesiologist, an imaging expert, and clinical support staff.

No doubt there is continual improvement in the transcatheter valves and their delivery system, the aim of which is offer this technology to a larger population with the privilege of treatment with minimal suffering and less pain. However, this technology still has imperative limitations and cannot be proposed to all patients with aortic valve stenosis. Until all limitations are surpassed and TAVI technology optimized, the advice remains to have multidisciplinary Heart Team discussions to optimize the selection process for the best TAVI candidates.

References

1. Alpert, J. S. Aortic stenosis in the 21st century. Am. J. Med. 123, 875–876 (2010).

2. He, W., Goodkind, D. & Kowal, P. International Population Reports. 175

3. Coffey, S., Cox, B. & Williams, M. J. A. The Prevalence, Incidence, Progression, and Risks of Aortic Valve Sclerosis: A Systematic Review and Meta-Analysis. J. Am. Coll. Cardiol. 63, 2852–2861 (2014).

4. Lester, S. J., Heilbron, B., Gin, K., Dodek, A. & Jue, J. The natural history and rate of progression of aortic stenosis. Chest 113, 1109–1114 (1998).

5. Al-Adhami, A. & Al-Attar, N. Recent advances in aortic valve replacement for aortic stenosis. F1000Research 5, (2016).

6. Charlson, E., Legedza, A. T. R. & Hamel, M. B. Decision-making and outcomes in severe symptomatic aortic stenosis. J. Heart Valve Dis. 15, 312–321 (2006).

7. Iung, B. et al. Valvular heart disease in the community: a European experience. Curr. Probl. Cardiol. 32, 609–661 (2007).

8. Kolh, P., Kerzmann, A., Honore, C., Comte, L. & Limet, R. Aortic valve surgery in octogenarians: predictive factors for operative and long-term results. Eur. J. Cardio-Thorac. Surg. Off. J. Eur. Assoc. Cardio-Thorac. Surg. 31, 600–606 (2007).

9. Cribier, A. Development of transcatheter aortic valve implantation (TAVI): a 20-year odyssey. Arch. Cardiovasc. Dis. 105, 146–152 (2012).

10. Nishimura, R. A. et al. 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J. Am. Coll. Cardiol. (2017). doi:10.1016/j.jacc.2017.03.011

11. Baumgartner, H. et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. Eur. Heart J. 38, 2739–2791 (2017).

12. Webb, J. et al. Multicenter evaluation of a next-generation balloon-expandable transcatheter aortic valve. J. Am. Coll. Cardiol. 64, 2235–2243 (2014).

13. Reardon, M. J. et al. Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients. N. Engl. J. Med. 376, 1321–1331 (2017).

14. Thourani, V. H. et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. Lancet Lond. Engl. 387, 2218–2225 (2016).

15. Thyregod, H. G. H. et al. Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis: 1-Year Results From the All-Comers NOTION Randomized Clinical Trial. J. Am. Coll. Cardiol. 65, 2184–2194 (2015).

16. Bourguignon, T. et al. Very long-term outcomes of the Carpentier-Edwards Perimount valve in aortic position. Ann. Thorac. Surg. 99, 831–837 (2015).

17. First look at long-term durability of transcatheter heart valves: Assessment of valve function up to 10-years after implantation - Google Search. Available at: https://www.google.com/search?q=First+look+at+long-term+durability+of+transcatheter+heart+valves%3A+Assessment+of+valve+function+up+to+10-years+after+implantation&ie=utf-8&oe=utf-8&client=firefox-b. (Accessed: 10th June 2018)